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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,655

06/20/2006

Paul J Bobrowski

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8863

26948

7590

07/14/2009

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EXAMINER

HOFFMAN, SUSAN COE

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

07/14/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@vclmlaw.com

Office Action Summary	Application No. 10/596,655	Applicant(s) BOBROWSKI, PAUL J	
	Examiner Susan Coe Hoffman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009 and 07 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-16 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment to the claims filed April 30, 2009 has been received and entered. The amendment to the specification filed January 7, 2009 has been received and entered. The response filed January 7, 2009 has been received and considered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1-13 and 17-20 have been cancelled.
3. Claim 21 has been added.
4. Claims 14-16 and 21 are pending.

Election/Restrictions

5. Newly submitted claim 21 is directed to an invention that lacks unit with the invention originally claimed for the following reasons:

Newly submitted claim 21 is directed to a method of treating degradation of cartilage and increasing the production of chondrocyte IGF-1 using a composition extracted from *Lepidium*. Original claims 14-16 are directed to a *Lepidium* extract composition. The composition and the method lack unity because the composition is taught by Zheng (US 6,267,995) while the method of treatment is not explicitly disclosed in Zheng. Zheng teaches a *Lepidium* composition with concentrated polysaccharides and a low lipid concentration. However, the reference does not teach using this composition to increase IGF-1 production or decrease degradation of cartilage. Thus, there is a lack of corresponding special technical feature between the composition and the method of using the composition.

Art Unit: 1655

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6. Claims 14-16 are examined on the merits.

Priority

7. Applicant has amended the specification to state that this application is a continuation in part of U.S. Application No. 10/676,266 which is a continuation in part of U.S. Patent Application No. 09/655,598 which claims benefit of U.S. Provisional Application No. 60/152,468. It is noted that applicant included the reference to these applications in the amendment filed January 7, 2009 and in the amendment filed November 20, 2006. However, if the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference

Art Unit: 1655

required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

8. In this case, the filing date of the current application is June 20, 2006 and the filing date of 10/676,459 is September 30, 2003. The specific reference to the prior application originally submitted on November 20, 2006 was later than both four months from the filing date of this application and sixteen months from the filing date of the prior application. Thus, the claim for priority to 10/676,459 and its parents cannot be granted unless applicant files a grantable petition to accept an unintentionally delayed benefit claim described above.

Claim Rejections - 35 USC § 112

Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 14 is indefinite because it is unclear what it meant by the phrase "subsequent depletion of aqueous properties." It is unclear if applicant means that aqueous ingredients are removed from the Lepidium and solvent mixture. For the sake of examination, this statement is considered to mean that the extract is concentrated to reduce solvent and any aqueous components that are present in the Lepidium plant extract. However, clarification is needed.

10. Claims 15 is indefinite because it states that the solvent used can be methanol but does not require aqueous methanol. Claim 14 states that the "aqueous properties" are "depleted." Since the methanol claimed in claim 15 is not aqueous, it is unclear if this solvent must be removed from the extract to form the claimed composition.

Claim Rejections - 35 USC § 102

11. Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng (US 6,267,995) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that Zheng does not qualify as prior art because this application is entitled to benefit from Provisional Appl. No. 60/152,468, filed September 3, 1999. However, as discussed above, the claim for priority to this provisional application cannot be granted at this time because the claim for priority was not filed within the

Art Unit: 1655

specified time periods set forth in 37 CFR 1.78(a)(2). Furthermore, even if priority to the provisional application was granted, Zheng would still qualify as prior art under 102(e) because the filing date of Zheng, March 3, 1999, is prior to the September 3, 1999 filing date of the provisional application.

Applicant also argues that the reference composition does not anticipate the claimed composition because the reference does not teach that the composition is able to enhance chondrocyte IGF-1 production or negate the degradation of cartilage. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The prior art composition is made by extracting *Lepidium* with aqueous methanol and then concentrating the extract to remove the solvent. This process results in a composition with concentrated polysaccharides and reduced lipid components. This composition is then formulated into pharmaceutical dosage forms (see column 1, lines 32-26, column 3, line 31, column 5, lines 16-18 and column 9, last paragraph). Thus, the reference composition is structurally the same as the claimed composition. Therefore, the prior art composition would be capable of performing the intended use and properly anticipates claims 14-16.

12. No claims are allowed.

Art Unit: 1655

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1655

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Coe Hoffman/

Primary Examiner, Art Unit 1655